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Research Article

Evaluation of a polyherbal gel in a single-arm open-label trial for management of scalp Pityriasis capitis (Dandruff)

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Abstract

Background: Pityriasis Capitis (Dandruff) is a leading scalp disorder, which affects over 50% population globally. Current anti-dandruff chemical based products can show side-effects, especially after long-term use. The ten herbs mentioned in *Kandughna* (anti-itching*)* class of *Charak Samhita* are known to have anti-itching effect along with proven anti-microbial and anti- inflammatory properties, which could potentially have strong anti-dandruff activity through the synergistic action of the contents. The traditional dosage form of paste or concoctions was converted into gel form i.e. *Dashemani Kandughna* Gel (DKG) for better patient acceptability. The developed gel, proven to be a stable and non-irritant formulation with significant in-vitro anti- microbial activity against dandruff causing organisms. *Objectives*: This single arm open label trial was designed to assess the clinical efficacy of *Dashemani Kandughna* Gel in the patients of dandruff. *Methods*: The gel was prepared by following the SOP and was assessed for its clinical efficacy through a single-arm non-randomized clinical trial conducted on 120 patients suffering from varying grades of dandruff. Gradation scale for major signs and symptoms i.e. itching, scalp dryness, scalp scaling and falling of hair, as well as trichoscopic examination were used as assessment criteria. The 21-day trial consisted of night-time topical drug application with 7 day follow-ups. *Results:* The statistical analysis showed that polyherbal gel has produced significant results (p- value < 0.05) with reduction of itching (90%), dryness (70%), scaling (79.35%). falling of hair (52%) The study corroborates the anti-dandruff activity of Polyherbal gel.

Keywords: *Darunak, Dashemani Kandughna Gel, Trichoscopy, Itching, Hair fall, Dryness.*

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Introduction

Hair and skin care play a vital role in one's appearance and youthfulness. Proper scalp care is crucial for both healthy hair and preventing scalp and hair-related issues.(1) Factors like an imbalanced diet, environmental pollutants, and inadequate hair care can negatively impact the scalp, leading to various scalp disorders, including dandruff (2). Ayurvedic literature identifies '*Darunak*' as a predominant scalp disease with symptoms resembling dandruff, such as itching, hair loss, dryness, and scaling.(3) It is a disease caused by vitiation of *Vata* and *Kapha* due to various dietary and lifestyle attributes and its manifestation is seen on the scalp skin. While dandruff affects about 50% of adults worldwide, approximately 18.38% of the Indian population is affected.(4) Various anti-dandruff products, including shampoos and creams, have been used, some containing chemicals that may have side effects. Researchers have explored herbal and Ayurvedic products to treat dandruff.

A group of ten herbal drugs, anti-itch group (*Dashemani Kandughna gana*) recommended in *Charak Samhita Sutrasthan* Chapter 4, including *Raktachandan* (*Pterocarpus santalinus Linn.*), *Jatamansi* (*Nordostachys jatamansi DC*), *Aragvadh* (*Cassia Fistula Linn*), *Naktamal* (*Pongamia pinnata Linn.*), *Neem* (*Azadiracta indica A.Jusss*), *Kutaj* (*Holarrhena antidysenerica Roth*), *Sarshap* (*Brassica campestris linn.*), *Madhuk* (*Glycerhhiza glabra Linn.*), *Daruharidra* (*Berberis aristata DC*), and *Musta* (*Cyperus rotundus Linn.*), possess anti-itching, antibacterial, anti-inflammatory, wound-healing, and skin-disease-curing properties. (5,6,7,8,9) These herbs are traditionally combined in powder or decoction form to alleviate itching symptoms across various formulations in Ayurvedic literature. However, this approach can be cumbersome, leading to low patient compliance. Gel formulations, being non-greasy and easy to apply with longer skin adherence, are more suitable for hair and scalp care.(10) The authors previously developed and standardized a polyherbal gel made from these ten herbs and have conducted in-vitro studies to

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establish its effectiveness against microorganisms known to be associated with dandruff (11).

This study was undertaken to explore the clinical efficacy of the developed polyherbal gel (DKG) in managing dandruff. Assessment was done using trichoscopy results and improvement in clinical symptoms to evaluate the effectiveness of the local application of the polyherbal gel (DKG).

Materials & Methods

Study design

The clinical efficacy of topical application of DKG was assessed through a single-arm non- randomized open-label clinical trial. Prior to clinical study, approval from Ethics Committee was obtained (REF: BVDUCOA/EC/2484/2020-21). The trial was registered with CTRI. The registration number for this trial is CTRI/2020/12/030010. (annexure no 1.). The clinical study was conducted on 120 patients of dandruff with consecutive 21 days intervention for each of the enrolled patients. The duration of the entire study was February 2021 to Nov 2022.

Sample Size Calculation:

The sample size was calculated using the following formula

$$n = \frac{z^2 pq}{e^2}$$

(Where, z is desired confidence level, p is p value, q is (1-p) and e is margin of error.)

Calculation

$$n = \frac{(1.96)^2(0.5)(0.5)}{0.09^2} \quad = 118.57 \sim \text{rounded off to } 120.$$

Sampling Method: Purposive sampling method was used to enroll screened patients befitting the inclusion criteria.

Blinding: No blinding was done as this was an open label single arm clinical study

Randomization: All enrolled patients were allocated to the intervention group.

Study drug

DKG was prepared at GMP certified pharmacy by following the standard operating procedure (SOP). Raw materials were procured from vendor and authentication of the samples was done from Agharkar Institute (annexure no.2). For the preparation of DKG, a decoction (30 litre) of ten herbs of *Kandughna gana* was prepared. Coarse powder of each drug from *Dashemani Kandughna Gana* was taken in 1.5 kg quantity in a stainless- steel vessel. 240 liters of water was added and the vessel was placed on low medium flame till 30 liters (1/8th) quantity remained. The temperature was maintained at 85-90º C.(12) This decoction was cooled down to normal temperature strained through a sieve to obtain clear liquid. Carbopol 934P (1% concentration – i.e. 3.2 kg quantity) as gelling agent, Glycerol (11.5 kg) as humectants, & DMDM as a preservative (3.2 kg) was added. The mixture was kept for 6-7 hours to allow the dispersion of Carbopol. With the aid of overhead mechanical stirrer set at 1200 rpm, a homogeneous gel was obtained. Obtained homogeneous mixture was neutralized with quantity sufficient of Triethanolamine (5.74 kg) with continuous stirring until it was converted into desired gel consistency and pH. The prepared batch was tested for its physico-chemical parameters and found to be within normal range (11). (annexure no.3)

Table 1: Parameters and Observations

Sr. No.	Parameters	Observations
1	Description Color Odor State	 Yellowish Brown Pleasant Semisolid
2	Visual Appearance	Transluscent
3	Homogeneity	Consistent
4	pH	6.98
5	Viscosity (cps) At 20 RPM At 100 RPM	 34500 9450
6	Spreadability	Easily Spreadable 0.6g.cm/s
7	Irritancy Test	No inflammation &irritation observed
8	TLC: Tannins TLC: Flavonoids TLC: Saponins	0.47 0.44 0.64

Participants

Dandruff patients between the age group of 18-50 years were screened at OPD level for enrollment process. Other patients suffering from seborrheic dermatitis, psoriasis of scalp, eczema of scalp, immune compromised conditions and suffering from systemic infections and those undergoing other treatment modalities were excluded.

Patients befitting the inclusion criteria were counseled through verbal communication and were also provided information sheets regarding the trial in English and local language (annexure no.4). The interested patients were enrolled in the study after obtaining written informed consent (annexure no.5). For the initial assessment, the enrolled patients were instructed not to wash hair two days prior to the appointment. On day one, a case report form (CRF) was filled (CRF) included general, demographic, and personal health details, *prakriti* analysis, dietary/lifestyle and hair care habits (annexure no.6). The initial assessments for dandruff assessment was done based on gradation of Itching *(Kandu),* Falling of hair (*Keshachyuti),* Dryness (*Rukshata), and* Scaling/ cracking of skin (*Twaksputana*) based on patient's description visual inspection (12). Following this, trichoscopy was done using digital trichoscope with X50 magnifying power to examine the scalp. For this assessment, the scalp was divided in four zones (viz. frontal, right parietal/temporal, left parietal/temporal, occipital) & gradation on a scale of 0-5 was done. The highest score observed was recorded as the trichoscopy grade.

Interventions

After initial assessment, packaged polyherbal gel jar of 220 mg for 21 days application and patient diary (annexure no.7) were given to each patient. Clear instructions regarding dose and time of application were given. The patient was asked to apply approx 10g or 1 tablespoon of the gel with clean fingers on the entire scalp at night time. They were instructed to follow their regular routine of combing, hair washing and hair oil application. To maintain the record, patients were asked to write daily application, any drops in application and untoward effects or allergic reactions, if any, in the patient diary. Daily telephonic communication was also done with patients during their course of treatment. Patient with four or more drops in application were considered as dropped out. Follow-ups were taken on day seven and day fourteen for

subjective parameters. Final assessment including trichoscopy was carried out on twenty second day (after completion of intervention). 21 days intervention was planned as per reference from Ayurved classics for treatment of *Kshudra Rogas.*(13)

Outcome measures

Clinical Assessment

Gradation of the cardinal signs and symptoms of dandruff i.e. itching, dryness, scaling/ crackling of skin and falling of hair was done as per Table 2 (14). The assessment was done on Day 1, Day 7, Day 7 and Day 22 of the intervention.

Table 2: Gradation of Symptomatic assessment (14)

Parameters / Gradation	Grade 0	Grade 1	Grade 2	Grade 3
Itching	No Itching	Mild, Tolerable (1to 2 Moderate, Intolerable times a day)	(3 to 4 times a day)	Severe, Intol (5 to 8 times Severe erable a day)
Dryness	No Dryness	Mild Dryness with Moderate	Dryness rough skin with scaling	Dry with cracking Severe ness skin plete
Scaling / cracking of skin	No scaling	Mild scaling 1/4th part	Moderate scaling is usually on vertex more than 1/2 part	Severe com scaling
Falling of hair	1 to 5 hair fall on washing	Mild (less than 20 hair fall on combing / washing)	Moderate (more than 20 hair fall on combing / washing)	Severe (Less than 20 hair fal on hand simple strength)

Trichoscopic Assessment (15)

Using Digital Trichoscope (X50 magnifying power), trichoscopic gradation was done. The scalp was divided into four zones and examined with the trichoscope. The score for each zone was noted and the highest score was recorded as the trichoscopy grade for the patient. This assessment was done on Day 1 and Day 22 of the intervention.

Table 3: Trichoscopic gradation (ASFS) (15)

Grade	Standards
0	No scales
1	Thin scales
2	Diffused thin scales
3	Thick heaped-up scales but not forming plaques
4	Diffused thick heaped-up scales but not forming plaques
5	Very thick heaped-up scales forming plaques

Statistical analysis plan

The data collected throughout the study was analyzed for Ayurvedic parameters of day 1, 7, 14 and 22, as well as trichoscopic findings of day one and day twenty-two were statistically analyzed using Wilcoxon Signed Rank test. Reduction in grades of clinical symptoms and trichoscopy by minimum of two grades was considered for positive effect of DKG.

Results

Enrollment

Total136 patients were screened, out of which 127 patients fulfilled eligibility criteria. Out of 127 eligible patients, one patient was not interested to participate in the study while six patients discontinued the application of DKG, thus were treated as drop-outs. Total 120 patients completed the study.

Baseline characteristics of participants

Table 4: Demographic, dietary and lifestyle observations

Sr.No	Parameters	Results					
1	Age	18-20 yrs 14.17%	21-30 yrs 35.00%	31-40yrs 34.17%	41-50 yrs 16.67%	NA	NA
2	Gender	Male 22.50%	Female 77.50%	NA	NA	NA	NA
3	Prakruti	Vataj 21.63%	Vata-kaphaj 18.33%	Pitta-Kaphaj 14.7%	Vata-Pittaj 10%	Kaphaj 7.50%	NA
4	Diet consumption	Mixed 72.50%	Veg 27.50%	NA	NA	NA	NA
5	Taste Dominance	Sweet 38.33%	Sour 39.17%	Pungent 76.67%	Salt 33.335%	Bitter 3.33%	Astringent 1.67%
6	Sleep	Regular 31.67%	Disturbed	Irregular 55.00%	NA	NA	NA

In the demographic, dietary, and lifestyle analysis, a notable observation emerged: a significant portion of female patients, aged between 19 to 40 years, exhibiting *Vataja* and *Vata-Kaphaja* constitutions, showcased irregular sleep patterns were afflicted by dandruff. A predominant dietary pattern emerged, with a notable preference for mixed diets featuring pungent, sour, and sweet taste profiles. These findings suggest a potential interplay between constitutional types, dietary choices, sleep patterns, and onset of dandruff within this specific demographic cohort as shown in Table 1.

Table 5: Hair care habits of the study population

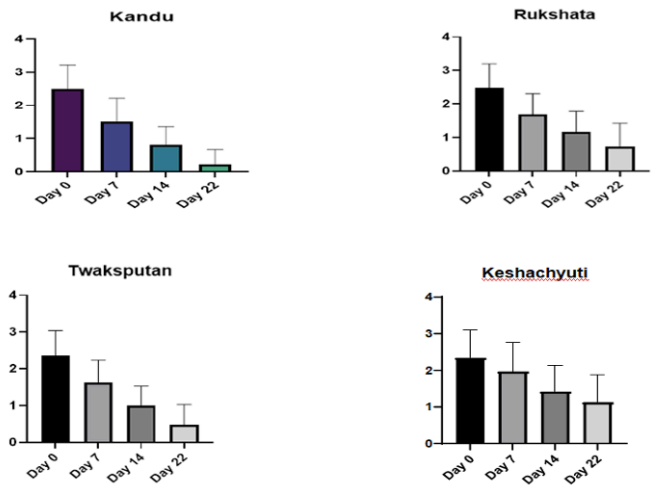
Sr. No.	Parameters	Results			
1	Density of hair	High – 75.00%	Medium – 1.67%	Low – 23.33%	NA
2	Scalp Condition	Dry – 90.00%	Oily – 6.67%	Normal – 3.33%	NA
3	Hair wash frequency	Daily – 05.83%	Alternate day – 10.83%	Weekly twice – 34.17%	Weekly once – 49.17%
4	Hair wash Material	Ayurvedic – 09.17%	Chemical – 90.83%	NA	NA
5	Comb tooth	Narrow – 91.00%	Wide – 09.00%	NA	NA
6	Hair Combing	Once – 44.17%	Twice – 49.17%	Three times – 05.00%	Four times – 01.67%

7	Oil application	Almond oil – 02.50%	Ayurvedic (polyherbal) – 15.83%	Coconut oil – 70.83%	No – 10.83%
8	Heat treatment	Blow drying – 34.17%	Sun Exposure – 37.50%	No – 28.33%	NA
9	Hair dyes	No – 30.00%	Henna-based – 46.66%	Permanent – 2.50%	Temporary – 20.83%

The present study identified a predominant occurrence of individuals with a high hair density and dry scalp. Among these patients, a prevalent hair care regimen involved weekly usage of chemical- based shampoos. Additionally, a majority reported daily hair combing using narrow-tooth combs, along with the application of plain coconut oil and henna-based hair dyes. Sun exposure and blow drying were common practices for hair drying among the surveyed population (Table 2). Observations for the symptoms of dandruff (Ayurvedic and trichoscopy) are on ordinal scale (gradation) thus, Wilcoxon Signed Rank test was used to assess the efficacy of polyherbal gel. Significant results were obtained in each assessment parameters as p value is <0.05.

Primary outcome measures results

Figure 1: Effect of DKG on observed grades before and after treatment in signs and symptoms of dandruff



In figure 3, the comparison of each of the 120 patient's trichoscopic grade before and after treatment is denoted. It can be noted that patient 1 showed overall grade 4 before treatment which was reduced to Grade 1 after 21 days of treatment, and so on for every consecutive. It is evident that none of the patients showed an increase in trichoscopic grade after treatment. 2.50% patients had shown reduction of scales of dandruff by difference of 1 Grade, 44.17% patients showed shown reduction by difference of 2 Grades, while 50% and 3.33% patients had shown reduction in scaling by a difference of 3 and 4 grades respectively.

Figure 2: Graphical presentation of Trichoscopic examination of scalp before and after treatment

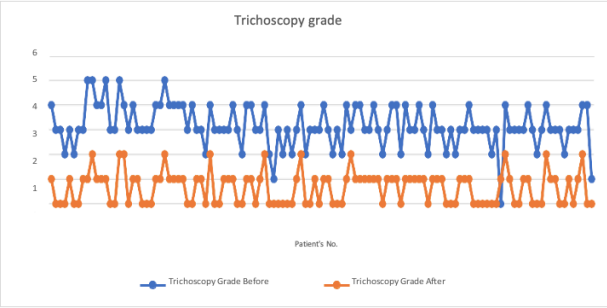
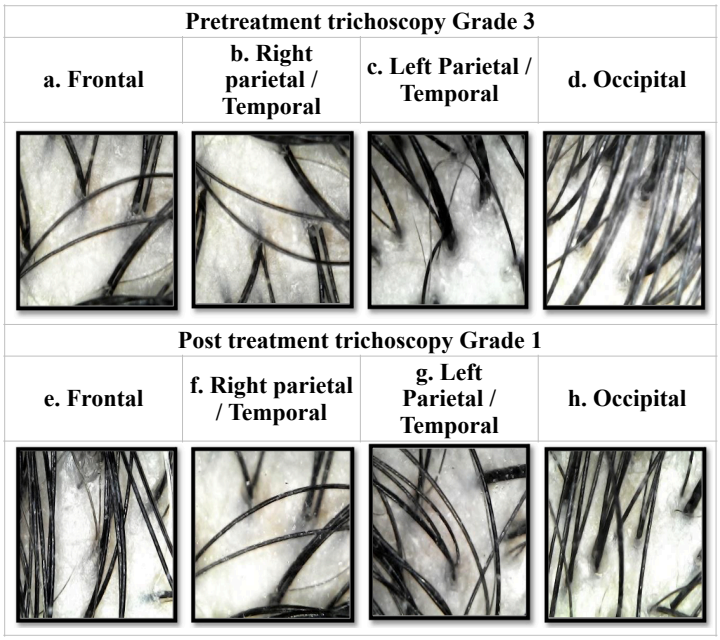


Figure 3: Trichoscopy photographs of scalp of randomly selected patient before and after treatment



Tolerability & Safety

It was observed that out of 120 patients, no adverse effects or sensitivity reactions were reported throughout the study. Therefore, it can be inferred that the prepared polyherbal gel product is safe for topical use on scalp skin.

Discussion

Dandruff presents more of a socio-psychological concern than a strictly medical one. Contemporary treatment typically involves a range of chemical and herbal products, either prescribed by physicians or bought over-the-counter. Traditional Ayurvedic medicine offers herbal remedies for scalp disorders like dandruff. Most of these traditional medicines are administered in dosage forms like decoctions, pastes, powders etc, which have low patient acceptability due to tedious preparation and application process. With nearly half of the global population affected by dandruff, current treatments often provide only temporary relief with potential side effects of chemical-containing products, leading to recurrent issues.(15) There is a pressing need for a lasting solution that addresses both symptoms and underlying causes. In the Sutrasthan Chapter 4, Acharya Charak has classified a group of drugs as *Kandughna*, comprising the aforementioned ten herbs with anti-itching properties, which are particularly beneficial for conditions like dandruff where itching is prominent symptom. These drugs are also effective in managing various other skin disorders such as eczema, rashes, dermatitis, and scaling issues. Often administered by Ayurvedic physicians in the form of powder or decoction, these can prove to be a hassle for administration in this modern era. DKG is an innovative dosage form developed using decoction these ten herbal drugs as base. It has proven anti-microbial activity against dandruff causing micro-organisms such as *Candida albicans, Malassezia furfur* and *Staphylococcus aureus*.(11) The gel form is also more easily

acceptable by patients rather than tedious preparation and application of pastes or decoctions. The ancient Ayurvedic practice of applying treatments at night time to be throughout night for conditions affecting the head and neck region, known as *Urdhwajatrugat rog*, has been found to be suitable due to increased permeability of the skin during night time (16,17). Consequently, the bedtime period was selected for the administration of DKG to achieve optimal results. The Ayurveda classic *Yog Ratnakar* has directed 21-day treatment period for scalp disorders.(13) Thus, DKG was applied for twenty-one consecutive days, leading to a gradual reduction in dandruff symptoms over the treatment period, signifying the adequacy of the twenty-one-day duration in achieving significant therapeutic outcomes. It was observed in this collected demographic data that the majority of patients fell within the young to middle age bracket (21-40 years), a period recognized for heightened susceptibility to dandruff due to hormonal changes stimulating sebaceous gland activity and subsequent sebum accumulation on the scalp, potentially exacerbated by the prevalent use of chemical hair products.(18) Additionally, a significantly higher proportion of female patients (78%) compared to males (22%) was noted, likely attributed to challenges in maintaining hair hygiene, especially with longer hair in females. Dietary factors, particularly the consumption of spicy, sour, sweet, or salty foods, along with irregular sleep patterns and exposure to heat, were identified as potential contributors to dandruff occurrence.(2) It was also observed that more than half i.e. 51.67% of the participants were of *Vata* and *Kapha* related *prakritis*, which is relevant as *Darunaka* according to Ayurveda is a disease caused by vitiation of *Vata* and *Kapha* (19) Moreover, the study observed that improper hair care practices, such as infrequent combing with a narrow-tooth comb (91%), and the predominant use of chemical-based shampoos(90.83%) and hair dyes(70%) among patients, may have further exacerbated scalp issues by stripping away moisture and natural oils, leading to increased dryness and susceptibility to microbial growth.(20) Similarly, the lack of regular combing (93.34%) and hair washing (49.17%), combined with exposure to heat(71.67%) were identified as aggravating factors for scalp dehydration and the development of dry, flaky skin.(21)

In terms of treatment, the polyherbal gel administered over a 21 days period, demonstrated significant overall efficacy in reducing dandruff symptoms, particularly itching, as evidenced by both clinical and trichoscopic evaluations. Ayurvedic criteria for assessment were applied based on a previous study, while grading for trichoscopic evaluation followed the methodology outlined by Bhattacharyya et al. The results of the current clinical investigation demonstrate that DKG exhibited statistically significant effects ($p< 0.05$) in reducing symptoms such as itching (Kandu) by 90%, dryness (*Rukshata*) by 70%, skin fissures (*Twaksphutan*) by 79.35%, and hair loss (*Keshachyuti*) by 52%. These findings were further supported by trichoscopic assessments, which showed an overall improvement in dandruff severity from higher to lower grades (%). Notably, the greatest efficacy was observed in alleviating itching, validating the anti-itching properties of both the *Kandughna Gana* class and the formulated DKG product. Additionally, a reduction in trichoscopy grades by 2 to 3 levels was noted in 45% and 49.17% of patients respectively, indicating the efficacy of DKG in reducing dandruff. Throughout the treatment period, there were no instances of relapse or exacerbation of dandruff severity, and no adverse reactions or allergies were reported among patients using the DKG product, underscoring its safety and tolerability for topical application. However, a relatively lower efficacy (52%) in reducing hair fall was observed, suggesting the potential need for extended application duration or increased frequency for patients experiencing hair loss. Overall, moderate to marked improvement was observed in 93.34% of the study population, highlighting the significant anti-dandruff activity of the DKG product. The mechanism of action of DKG, attributed to its synergistic blend of herbs with predominantly *katu*, *tikta*, *kashaya rasa* and *ushna veerya* properties that contributed to alleviate scales, dryness, and itching of the scalp skin. This is because, *tikta, Katu Kashay rasa* and *Ushna Veerya* is known to alleviate *kapha*- the *dosha* responsible for causing dandruff as well as its cardinal symptom *kandu*. Additionally, *katu rasa* and *ushna veerya* are known to alleviate *vata*- a contributing factor in *samprapti* of *darunaka* as well as the symptoms of dryness and scaling. Furthermore, the presence of flavonoids, tannins, and saponins in DKG herbs was identified as conferring antimicrobial and antioxidant properties, contributing to its efficacy as an anti-dandruff agent.(22,23,24) In contrast, conventional treatments for dandruff primarily rely on synthetic drugs targeting specific factors such as Malassezia yeast proliferation or epidermal barrier dysfunction, although the exact mechanisms of action remain unclear.(25) Similarly, while the precise mechanism of DKG action is not fully elucidated, its formulation principles based on Ayurvedic literature suggest a holistic anti-dandruff action while also leveraging the synergistic anti- microbial effects of constituent herbs with complementary properties to address scalp issues effectively. The antimicrobial activity of DKG is already established against microorganisms known to cause dandruff i.e. *Malassezia furfur*, staphylococcus aureus and *candida albicans*

Previous research studies have focused on formulating herbal gels utilizing alcoholic extracts as the primary active ingredients. However, certain cosmetic formulations, including gels containing parabens (such as methyl, ethyl, propyl, isopropyl), have been associated with potential skin irritation and systemic side effects upon prolonged use.(26) In contrast, the newly developed DKG, polyherbal gel formulation, prepared using aqueous extracts (decoction) and incorporating the safer preservative DMDM, exhibited effective management of dandruff without adverse effects. Patients reported favorable experiences with the DKG product, noting its non-greasy texture and the softening effect it imparted to their hair after washing. No adverse reactions, such as redness or inflammation of the scalp, were reported, indicating good tolerability of the DKG product among users.

Limitations and further scope of study

The present study, conducted as an open-label, single-arm investigation, aimed to provide evidence of the efficacy of the innovative gel dosage form using *Kandughna Gana*. However, future research endeavours should include comparative assessments of polyherbal gel (DKG) against other commercially available anti-dandruff products to better understand its comparative efficacy. The pathway elucidation can be explored to understand the exact mechanism of action of the product DKG. Additionally, exploring the potential of polyherbal gel in managing other scalp infections through prolonged application periods and conducting comparative clinical studies on larger patient populations can further validate its efficacy and broaden its therapeutic utility beyond dandruff management.

Conclusion

The herbal decoction from the *Dashemani Kandughna gana*, used as a base for a topical dosage form, was successfully reformulated into a new product i.e. a gel in aqueous base. After evaluating

Ayurvedic parameters and trichoscopy grades, DKG demonstrated a significant reduction (p-value<0.05) in dandruff symptoms. Therefore, it can be concluded that the anti-dandruff effect of the DKG product has been established and confirmed in this study.

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